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March 25, 2025

Via ECF

Honorable Evelyn Padin, U.S.D.J. United States District Court Martin Luther King Building & U.S. Courthouse 50 Walnut Street Newark, New Jersey 07101

Re: Novartis v. Novadoz et als.

Civil Action No. 2:25-cv-00849-EP-JRA

Dear Judge Padin:

We, along with our co-counsel at Daignault Iyer LLP and Jenner & Block LLP, represent Defendants Novadoz Pharmaceuticals LLC, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited (collectively, "MSN") in the above matter. We write to provide a brief response to Novartis's letter of March 25, 2025 (ECF 38) responding to MSN's letter for March 24, 2025 (ECF 36) regarding the briefing schedule on MSN's motion to stay the preliminary injunction (ECF 37).

First, MSN's letter did not state that it was, or otherwise purport to be, a joint letter. It simply accurately reported Novartis's position as it was conveyed to MSN. Nonetheless, we apologize for any misunderstanding in this regard.

Second, Novartis misrepresents the status of the parties' patent litigation. While the Federal Circuit held that Novartis's '659 patent is valid, it also held that the patent *does not cover sacubitril-valsartan complexes like Entresto* as a matter of law. *See In re Entresto*, 125 F.4th 1090, 1099 n.5 (Fed. Cir. 2025) ("Because valsartan-sacubitril complexes were undisputedly unknown at the time of the invention, the '659 patent could not have been construed as claiming those complexes as a matter of law." (citations omitted)). Because Novartis's '659 patent does not cover Entresto, Novartis is not entitled to pediatric exclusivity blocking the launch of MSN's generic drug product. After the mandate issues in the patent litigation, there will be no basis for the Delaware district court to further enjoin MSN. At that time (within seven days), this Court's preliminary injunction will be the only legal bar preventing MSN from launching its product, further underscoring the need for expedited briefing on MSN's motion to stay the preliminary injunction.

We appreciate the Court's attention to this matter.

Honorable Evelyn Padin, U.S.D.J. March 25, 2025

Respectfully submitted,

/s/ Rebekah Conroy Rebekah Conroy

cc: Counsel of Record via ECF

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